ISRCTN59443849 https://doi.org/10.1186/ISRCTN59443849

A feasibility study of prescribing chair based pedal exercises for older people admitted to hospital on function and mobility compared to standard care

Submission date
21/07/2015

Recruitment status
No longer recruiting

Registration date
27/07/2015

Overall study status
Completed

Last Edited
07/12/2017

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The British Heart Foundation recommends physical activity in frail older people. Unfortunately, older patients in hospital spend the majority of their time in a sedentary state. Physical inactivity in hospital leads to poorer health outcomes. Encouraging physical activity in hospital is challenging due to a number of reasons ranging from a limited number of therapists (who usually deliver the exercise sessions), limited therapy time, older patients unable to recall exercises prescribed, lack of patient engagement and motivation; and concern of causing falls. Therefore, chair based pedal exercises offer a simple method of improving physical activity. Its repetitive nature is much easier to follow and this helps those with memory concerns. Resistance training as part of pedal exercise may improve muscle strength. All this should result in improved lower limb function. An activity that involves sitting down is more likely to reassure both patients and staff regarding the risk of falls and resulting injury. Chair based pedal exercise in addition to usual ward care may improve healthcare outcomes. We propose a study to evaluate how feasible it is to deliver regular chair based pedal exercises (the intervention) on older people (≥65 years old) admitted to an acute medical ward.

Who can participate?
People aged at least 65 admitted to an acute geriatric ward that are able to co-operate and sit in a chair on their own for at least 10 minutes

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 receive standard care, that is the care currently given on the ward. Those in group 2 receive the intervention. This includes
regular chair based pedal exercises for 5 minutes 3 times a day until they leave hospital or after 7 days, whichever comes. This is in addition to the standard care delivered. Participants are asked to pedal continuously with no pre-specified targets set, e.g. rpm or level of resistance. This exercise is initially supervised by a member of the research team and then supervised by

members of the ward team. This is to replicate ‘real life’ hospital setting where exercises in hospital are initiated and observed by a therapist and the patients encouraged to continue with the exercises with support by the ward team. Participants in both groups have access to the ward physiotherapist and an inpatient therapy plan as part of their standard care. The participants also have similar access to medical, nursing and other allied healthcare staff.

What are the possible benefits and risks of participating?
Participants offered pedal exercises will be able to maintain their fitness whilst in hospital. Participating in the study will help to provide the research team with information to improve physical activity and mobility in hospital. There are no known side effects. Tiredness due to the pedal exercise is possible. Hence, if a participant suffers with any heart or lung problems, the research team would urge the participant to pace him or herself, to stop if any discomfort arises and inform the healthcare and research team. Participants may also experience mild discomfort from wearing the activity monitor with its associated dressing. If this was the case the monitor could be repositioned.

Where is the study run from?
Queens Medical Centre, Nottingham University Hospitals NHS Trust.

When is study starting and how long is it expected to run for?
October 2014 to October 2016

Who is the main contact?
Dr Terence Ong

Contact information

Type(s)
Scientific

Contact name
Dr Terence Ong

Contact details
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Additional identifiers

Protocol serial number
NUH R&I 14HC024

Study information

Scientific Title
The effect of chair based pedal exercises for older people admitted to an acute hospital on function and mobility compared to standard care: a feasibility study

Acronym
PEDAL

Study objectives
Chair based pedal exercise in addition to standard care improves muscle function in older people admitted to hospital compared to standard care alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Coventry & Warwickshire, ref: 15/WM/0149

Study design
Randomised feasibility trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Muscle strength of older people admitted to hospital

Interventions
There will be 2 treatment groups (standard care and intervention group).
1. Standard care is what is currently done on the ward.
2. The intervention is prescribed regular chair based pedal exercises for 5 minutes 3 times a day until discharge or 7 days, whichever comes first in addition to the standard care delivered. Participants will be asked to pedal continuously with no pre-specified targets set, e.g. rpm or level of resistance. This exercise will be supervised initially by a member of the research team with subsequent supervision by members of the ward team. This is to replicate 'real life' hospital setting where exercises in hospital are initiated and observed by a therapist and the patients encouraged to continue with the exercises with support by the ward team.

Both arms of the trial will have access to the ward physiotherapist and an inpatient therapy plan as part of their standard care. The participants will also have similar access to medical, nursing and other allied healthcare staff.

Intervention Type
Device

Primary outcome(s)
Muscle strength

Key secondary outcome(s))
1. Changes in mobility (Elderly Mobility Scale)
2. Physical activity (body worn accelerometers)

3. Inpatient falls
4. Discharge destination
5. inpatient and 30 day mortality

Completion date
10/10/2016

Eligibility

Key inclusion criteria
1. Older people (≥ 65 years) admitted as an emergency to an acute geriatric ward
2. Able to co-operate and able to sit in a chair independently for a continual period of at least 10 minutes

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Terminally ill or moribund
2. Need for isolation
3. Bed bound prior to admission
4. Predicted length of stay ≤48 hours
5. Unable to use the pedal exerciser due to functional impairment, e.g. lower limb fracture, lower limb pain, leg amputation, foot deformity

Date of first enrolment
10/08/2015

Date of final enrolment
01/04/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Research and Innovation, Nottingham University Hospitals NHS Trust

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Not defined

Funder Name
British Geriatrics Society

Alternative Name(s)
The British Geriatrics Society, The British Geriatrics Society (BGS), GeriSoc, BGS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Terence Ong, terenceong@doctors.org.uk. Anonymised participant level data will be available for analysis upon request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		02/11/2017	07/12/2017	No	No
HRA research summary			28/06/2023	No	No